No registrations found.

Ethical review	Positive opinion
Status	Completed
Health condition type	-
Study type	Observational non invasive

Summary

Source

NTR

Brief title

OKIDOKI-3

Health condition

Asymptomatic pneumococcal carriage, infectious diseases, Streptococcus pneumoniae, viral presence, bacterial commensals

Sponsors and support

Primary sponsor :	National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support :	Ministry of Health, Welfare and Sports

Intervention

Outcome measures

Primary outcome

The percentage of total vaccine- and non-vaccine pneumococcal serotypes found in the nasopharyngeal swabs from infants at 11 and 24 months of age by conventional culture. Serotyping is performed at single
colony level by Quellung reaction as in previous surveillance studies.

Secondary outcome

1. The percentage of total vaccine- and non-vaccine pneumococcal serotypes found in the nasopharyngeal swabs from parents of the 24-month-old infants as determined by culture and Quellung;

2. The percentage of infants and parents with nasopharyngeal swabs positive for S. aureus, H. influenzae and M. catarrhalis as determined by culture;

3. The percentage of individual pneumococcal serotypes found in the nasopharyngeal swabs from infants at 11 and 24 months of age and parents of the 24-month-old infants as determined by culture and Quellung.

Study description

Background summary

Surveillance of nasopharyngeal carriage of pneumococci is important to evaluate shifts in circulation of specific serotypes and to potentially make timely adjustments in the vaccination program. Previous surveillance studies were performed immediately before introduction of pneumococcal vaccination and 3 and 4.5 years after introduction, i.e. respectively the MINOES, OKIDOKI-1 and OKIDOKI-2 studies. The nasopharyngeal swabs collected during the current study will be assessed for the concurrent presence of other respiratory bacterial pathogens like S. aureus, H. influenzae, M. catarrhalis or viral pathogens like Influenza.

Study objective

Vaccination against pneumococcal bacteria results in eradication of nasopharyngeal colonization by pneumococcal serotypes present in the pneumococcal vaccine in vaccinated children and their parents but serotypes not included in the vaccine fill in the vacant niche. This replacement of serotypes is not random and new types become dominant and may cause disease. Pneumococcal serotype replacement may affect the presence of other commensals in the nasopharynx.

Study design

1. 11 month timepoint before the 11 month booster (11-month-old infant);

2. 24 month timepoint (24-month-old infant and parent).

Intervention

N/A

Contacts

Public
RIVM
Alienke Wijmenga-Monsuur
Bilthoven 3720 BA
The Netherlands
NA
Scientific
RIVM
Alienke Wijmenga-Monsuur
Bilthoven 3720 BA
The Netherlands
NA

Eligibility criteria

Inclusion criteria

1. Healthy infants;

2. Parents are willing and able to participate;

3. Infant is 11 or 24 months old (± 4 weeks) dependent on the group;

4. Infant received 3 pneumococcal vaccinations before the age of 6 months (11-month-old infant) and the 11 month booster (24-month-old infant);

5. Informed consent signed by both parents/legal representatives.

Exclusion criteria

Infants:

1. Previous vaccinations not according to Dutch 3+1 schedule;

2. Previous vaccinations with other pneumoccocal vaccines than Synflorix (11-month-old infant) or Prevenar-7 (24-month-old infant).

Infants and parents of 24-month-old infants:

1. Chromosomal abnormalities or craniofacial abnormalities (like Trisomy 21 or schisis), known or suspected immunodeficiency disease or other medical conditions that will severely affect immunological responses to vaccinations or nasopharyngeal carriage rates;

2. Coagulation disorder/anticoagulant medication.

Study design

Design

Study type :	Observational non invasive
Intervention model :	Parallel
Allocation :	Non-randomized controlled trial
Masking :	Open (masking not used)
Control :	N/A , unknown

Recruitment

NL

Recruitment status :	Completed
Start date (anticipated) :	01-10-2012
Enrollment :	990
Type :	Actual

IPD sharing statement

Plan to share IPD : Undecided

Ethics review

Positive opinion
Date : 18-09-2012
Application type : First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3462
NTR-old	NTR3614
Other	RIVM : VAC-264
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A